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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/797,958

03/10/2004

Stephen Brushey

DB000841-007

4864

20583

7590

12/11/2008

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

12/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Species A in the reply filed on 8/25/08 is acknowledged. The traversal is on the ground(s) that Species A and Species B are not mutually exclusive and therefore would not be a burden to examine. This is not found persuasive because the features included in Species C such as a conductive coil having adjacent turns spaced to enable fluid to leak are distinct from features included in Species A such as diffusion openings arranged in rows.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/651728, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112

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for one or more claims of this application. The prior-filed application fails to provide support for a conductive end cap and a conductive flexible member.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “34” has been used to designate both a reinforcement member and a flexible conductive member. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-9, 11-13, 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Massengale (US 2002/0052576) in view of Hafer et al (US6456874). Massengale discloses a fluid delivery catheter comprising a catheter having a distal tip comprising an end cap 348, and a

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plurality of openings 364, 372, 356, 404. The catheter has an inner diameter of 0.019 inches, and an outer diameter of 20 gauge (Page 12, paragraph 0133). The length of the diffusion area may be any desired length (page 12, paragraph 0137), but is preferably about 0.5 inches to 20 inches (page 13, paragraph 0140). The openings are inherently offset between 0 and 360 degrees. The openings may be arranged in rows. See Figs 18A-C. The adjacent openings may be spaced between 0.125 inches and 0.25 inches (page 13, paragraph 0140). The catheter may be formed of a sterilizable plastic such as polyamide (page 12, paragraph 0133).

5. Claim 1 differs from Massengale in calling for the end cap to be conductive and the device to further include a flexible conductive element attached to the end cap. Hafer teaches a catheter similar to that of Massengale, but further including a conductive end cap 72 and flexible coil 70 so that electrical stimulation can be utilized in locating the specific location of the catheter tip within the nerve (Col. 2, lines 34-41). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Massengale to include a conductive end cap and conductive flexible element as taught by Hafer so that electrical stimulation can be utilized to locate the catheter tip within the nerve.

6. Regarding claim 15, Hafer is silent as to the specific material of the conductive material. Hafer discloses that the flexible element and the end cap are formed of a conductive metal. It is well known in the art to use stainless steel in electrical stimulation devices because it is biocompatible and nonreactive. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to form the conductive flexible element from stainless steel.

7. Regarding claim 17, Hafer fails to disclose the dimensions of the wire. Where the only difference between the prior art and the claims was a recitation of relative dimensions of the

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claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See MPEP 2144.04.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Massengale in view of Hafer as applied to claim 1 above, and further in view of Beisel (US 5947940). Claim 10 differs from the teachings above in calling for a window for visualizing flashback. Beisel teaches an epidural catheter similar to that of Massengale but further including a window for visualizing flashback (Col. 3, lines 40-42). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Massengale to include a flashback window as taught by Beisel to assist the user in proper placement of the device.

9. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Massengale in view of Hafer as applied to claim 1 above, and further in view of Brushey (US 6676643). Claim 14 differs from Massengale in calling for the device to be formed of polyurethane and at least one siloxane. Brushey teaches that a device may be formed of polyurethane and at least one siloxane. Siloxane, commonly called silicone rubber, is well known in the medical arts for its flexibility and biocompatibility. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to form the device of Massengale of polyurethane and siloxane as taught by Brushey because both materials are commonly used for their flexibility and biocompatibility.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Laura A Bouchelle
Examiner
Art Unit 3763

/Laura A Bouchelle/
Examiner, Art Unit 3763
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